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SERIAL NUMBER	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
07/931,154	08/17/92	LUCIW	P 22300-20035.

EXAMINER	
WOODWARD, M	
ART UNIT	**PAPER NUMBER**
1813	4

DATE MAILED: 01/27/93

MORRISON & FOERSTER
755 PAGE MILL ROAD
PALO ALTO, CA 94303-1018

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

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☒ This application has been examined ☒ Responsive to communication filed on 8/17/92 11/30/92 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ___ days from the date of this letter. Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☒ Notice re Patent Drawing, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, Form PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____

Part II SUMMARY OF ACTION

1. ☒ Claims 1-59 are pending in the application.
   Of the above, claims _____ are withdrawn from consideration.
2. ☒ Claims 2-59 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 1 13 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable. ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____ has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on _____, has been ☐ approved. ☐ disapproved (see explanation).
12. ☐ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

This application appears to be a division of application Serial No. 07/138,894 filed 12/24/1987. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in the earlier or parent application, is known as a divisional application or "division". The divisional application should set forth only that portion of the earlier disclosure which is germane to the invention as claimed in the divisional application.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Claim 1 of this application conflicts with claim 1 of application serial number 07/931,191. 37 C.F.R. § 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See M.P.E.P. § 822.

The following is a quotation of the first paragraph of 35

U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, i.e. failing to provide an enabling disclosure.

Applicants do not provide enablement for all unicellular microorganisms. Applicants do not teach how one can determine what a replication system is nor how one can predict what replication systems a unicellular organism can recognize.

Applicants do not provide guidance as to how to select the DNA sequences from HIV other than those employed in the expression systems of the examples. No guidance as to which 20-mers of the more than 9170 possible has utility as a probe for HIV is provided. Applicants have provided an invitation to experiment to find those elements required for replication in microorganisms and those probes of at least 20 bp which permit detection of HIV sequences.

Claim 1 is rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

> 35 U.S.C. § 101 reads as follows:
> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claim 1 is provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claim 1 of copending

application Serial No. 07/931,191. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103.

Claim 1 is rejected under 35 U.S.C. § 103 as being unpatentable over Levy (US Patent 4,716,102).

At column 4, lines 25-43 Levy suggests cloning ARV nucleic acids into vectors suitable for replication in prokaryotes.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to clone fragments of or the entirety of the HIV genome into a prokaryotic vector

because it would facilitate sequencing of the genome and it would permit generation of nucleic acid probes without concomitant generation of infectious virus.

Claim 1 is rejected under 35 U.S.C. § 103 as being unpatentable over Barre-Sinoussi et al. (1983) in view of the level of skill in the art.

Barre-Sinoussi et al. (1983) teaches the isolation of HIV virus from patient sera. On page 870 right hand column it states "The DNA sequences of these and other members of the HTLV family are being compared." Isolating virus from patient sera is time consuming and dependant upon physiologic factors outside the control of the experimenter.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to clone the viral genome or portions thereof into a vector capable of replication in E. coli because this would overcome the difficulties of relying on patients as the source of virus. Applicant has admitted on page 4 of the specification that Arya et al. (1984) was known to them. Arya et al. teaches the production of cDNA from the HIV virus which indicates that this method of isolating viral nucleic acid for cloning would be expected to work. Arya et al. also teaches that the related HTLV viruses have been cloned in a lambda vector, thus there is a reasonable expectation of success that the HIV genome could be cloned into a lambda vector.

Claim 1 is rejected under 35 U.S.C. § 103 as being unpatentable over Montagnier et al. (US Patent 4,708,818) in view of the level of skill in the art.

Montagnier et al. teaches the isolation of the AIDS virus and its propagation in tissue culture.

Montagnier et al. does not teach cloning the AIDS genome in part or in whole in prokaryotic vectors. Nor does Montagnier et al. teach away from such cloning.

One of ordinary skill in the art would have been aware of several problems with using intact AIDS virus, e.g., the possibility of infection or the difficulty in obtaining large amounts of nucleic acid for sequencing studies.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to clone all or part of the AIDS viral genome into a prokaryotic vector because it would obviate the problem of infectivity and would permit the generation of large amounts of viral nucleic acid.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Woodward whose telephone number is (703) 308-3890.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 180 by facsimile transmission. Papers should be faxed to Group 180 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15,1989).

The CM1 Fax Center number is (703) 308-4227.

MP Woodward
January 22, 1993

CHRISTINE M. NUCKER
SUPERVISORY PATENT EXAMINER
GROUP 180

Question 12c

Debra A. Shetka - Reg. No. 33,309
Karl Bozicevic - Reg. No. 28,807
Felissa H. Cagan - Reg. No. 35,089
Barbara J. Luther - Reg. No. 33,954
Paul F. Schenck - Reg. No. 27,253
E. Thomas Wheelock - Reg. No. 28,825
Nancy Joyce Gracey - Reg. No. 28,216
Audrey E. Klein - Reg. No. P35,920